

## **8.0 510(k) Summary ( as per 21 CFR 807.92)**

### **I. GENERAL INFORMATION**

OCT 28 2009

**Device Generic Name:** Infrared Lamp

**Trade Name:** Nexus XPulse 805 IR Lamp System  
Nexus XPulse 980 IR Lamp System

**Device Classification:** Class II, Performance Standards  
21CFR Part 890.5500 – Infrared Lamp

**Product Code:** ILY

**Applicant Name and Address:** USA Laser Biotech Inc.  
9210 Forest Hill Avenue  
Richmond, VA 23235 USA  
Telephone: 877 / 423-6169

**510(k) Number:** ~~Pending~~ K 091726

### **II. Device Description**

The Nexus XPulse 805 and the Nexus XPulse 980 IR Lamp Systems (Figure 1) are intended for use as infrared heat lamps. The Systems are non-invasive devices that emit light energy to the skin-surface of human body for the purpose of causing the therapeutic elevation of tissue temperature.

The Nexus XPulse Systems deliver an invisible laser light beam in the infrared spectrum at wavelengths of 805 nm and 980 nm using a gallium aluminum arsenide (GaAlAs) source. The laser light beam is carried to the focusing lens on the handpiece probe by quartz optical fibers. The tissue to be treated is illuminated by a non-therapeutic red laser guide light.

The Systems consist of 2 main hardware sub-systems: 1) the control console and 2) the treatment handpiece probe with its connecting cable.

The control console is made of standard medical PVC material and is designed to be placed on a desktop or table in the vicinity of the patient to be treated. The console houses the user interface, which is a pressure activated membrane and an LCD display.

The treatment probe is made of standard medical grade PVC. The laser energy for heat treatment is delivered to the treatment probe via fiberoptic cables. The probe contains a focusing lens at the aperture, which is made of glass suitable for medical applications.

### **III. Indications For Use**

The Nexus XPulse IR Lamp Systems are intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

### **IV. Predicate Devices**

The Nexus XPulse 805 and 908 IR Lamp Systems are substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. These predicate devices include, but are not limited to, the USA Laser Biotech, Inc. LUMINA 1600 Infrared Heat Lamp Therapy System (K052814), and Avicenna Laser Technology, Inc. ALT Laser, Model VTR 75 (K031612).

### **V. Summary of the Technical Characteristics of the NET-1000 System as Related to the Referenced Predicate Devices.**

The Nexus XPulse IR Lamp Systems and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared and visible laser diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

### **VI. Testing**

Testing of the System includes functional performance testing and electrical safety testing. The Systems are manufactured to comply with the following international standards:

- EN 60601-1:2001 Medical Electrical Equipment, Part 1, General Requirements for Safety
- EN 60601-1-2:2001 Medical Electrical Equipment, General Requirement for Safety. Electromagnetic Compatibility
- ISO 14971 Medical Devices: Application of Risk Management

### **VII. Conclusions**

Pursuant to the testing and comparison to the predicate devices, the Nexus XPulse IR Lamp Systems have the same intended uses, with similar functional and performance characteristics. The System is designed to comply with applicable performance standards promulgated by Federal Food and Drug Administration. The Systems perform as intended and do not raise any new safety or efficacy issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

USA Laser BioTech, Inc.  
% Texas Applied Biomedical Services  
Ms. M. Joyce Heinrich  
12101 Cullen Boulevard, Suite A  
Houston, Texas 77047-2951

OCT 28 2009

Re: K091726

Trade/Device Name: Nexus XPulse 805 and Nexus XPulse 980 IR Lamp Systems  
Regulation Number: 21 CFR 890.5500  
Regulation Name: Infrared lamp  
Regulatory Class: Class II  
Product Code: ILY  
Dated: September 11, 2009  
Received: September 25, 2009

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

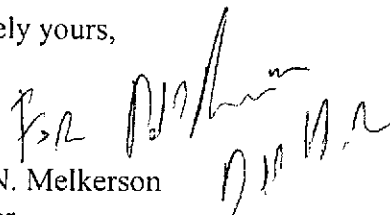
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**ATTACHMENT II**

**Indications for Use Statement**

**510(k) Number (if known):** **K091726**

**Device Name:**

Nexus XPulse 805 and Nexus XPulse 980 IR Lamp Systems

**Indications for Use:**

The Nexus XPulse IR Lamp Systems are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

**Prescription Use: X AND/OR Over the Counter Use: \_\_\_\_\_**  
**(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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**Concurrence of CDRH, Office of Device Evaluation (ODpE)**

*Nil R. [Signature]* for mkm  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number **K091726**